Manual Therapy by General Medical Practitioners for Nonspecific Low Back Pain in Primary Care: The ManRück Study Protocol of a Clinical Trial

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Abstract

Background: Nonspecific low back pain (LBP) is a common reason for accessing primary care. Manual therapy (MT) may be an effective treatment, but data from clinical studies including relevant subgroups and clinical settings are sparse. The objective of this article is to describe the protocol of a study that will measure whether an MT protocol provided by general medical practitioners will lead to a faster pain reduction in patients with nonspecific LBP than does standard medical care.

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Methods/Design: The study is an experimental pre-/postintervention design. The intervention consists of add-on MT treatment by general medical practitioners who have received MT training but are otherwise inexperienced in mobilization techniques. Participating general medical practitioners (n = 10) will consecutively recruit and treat patients before and after their training, serving as their own internal controls. The primary end point is a combined outcome assessing change in pain score over days 0 to 3 and time until pain is reduced by 2 points on an 11-point numeric pain scale and painkiller use is stopped. Secondary outcomes are patients' functional capacities assessed using a questionnaire, amount of sick leave taken, patient satisfaction, and referrals for further treatment.

Trial registration: German clinical trials register: DRKS-ID DRKS00003240.

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Introduction

Acute low back pain (LBP) is a major health problem accounting for frequent general medical practitioner (GP) consultations. Although spontaneous healing is the norm for nonspecific LBP,¹ the disease is costly because of the high number of visits to GPs and specialists and the sick leave incurred. Quality of life during the painful episode is poor, and there is a high risk that a chronic illness will develop.^{2,3}

The National Treatment Guidelines recommend maintaining physical activity and taking painkillers (ie, nonsteroidal antirheumatics as evidence-based therapeutic options).⁴ Manual therapy (MT) is another therapeutic option, although its effectiveness for acute LBP remains controversial. Although a systematic review from 2012 concluded that the addition of MT offers no benefit,⁵ more recent randomized controlled trials (RCTs) demonstrated positive effects of MT on pain and physical function.^{6,7} International guidelines differ in their recommendations regarding MT; whereas some are in favor, others strongly advise against its use.⁸

In Germany, MT is taught using several different approaches and techniques and is considered to be highly beneficial by more than 80% of GPs.⁹ More than 20 000 medical physicians, many of whom are GPs, have received training in MT from 1 of the 5 different schools.¹⁰ In Germany, MT is frequently administered in the general practice setting, an approach that has also proven feasible in other countries.^{11,12} In contrast to studies on MT where the treatment is mainly performed by chiropractors, manual therapists, and osteopaths,⁵ the ManRück study (Manuelle Therapie bei unspezifischen akuten Rückenschmerzen) addresses the effects of MT provided by medical GPs. Studies focusing on provision of MT by a GP during a clinical appointment are scarce. In addition, the number of GPs already certified to

administer MT is very low compared to the prevalence of LBP. As a positive effect of MT on acute LBP seems likely, we set out to determine whether training in MT for acute LBP can improve outcomes in primary care patients treated by GPs who are otherwise inexperienced in MT. Therefore, the objective of this article is to describe the protocol of a study that will measure whether MT provided by general practitioners leads to a faster pain reduction in patients with nonspecific LBP than does standard care.

Methods

Study Overview

The study is designed as a prospective, multicenter, pre-/postintervention study to evaluate the benefits of GPs' training in MT for patients with acute LBP. Participating GPs who are not trained in MT will consecutively recruit all patients with LBP who fulfill the inclusion criteria. In the preintervention (control) section of the study, the GPs will provide standard treatment for their patients according to the national guidelines. After receiving an expert-approved training in MT for acute LBP, these GPs will continue the consecutive recruitment of eligible patients. In this second postintervention section, all patients will receive MT in addition to the standard treatment. We assume that the use of MT will lead to a more rapid reduction in pain intensity as measured using a numeric pain scale.

An overview of the study design is shown in Fig 1.

As only low-force techniques will be used, the risk of harm for participating patients is considered negligible. Ethics approval has been granted by the Hannover medical school Ethics Committee (no. 6006).

Fig 1. Flowchart with an overview of the ManRück study design. *FFbH-R*, Funktionsfragebogen-Hannover; *GP*, general practitioner; *MT*, manual therapy; *NPS*, numeric pain scale.

Funding is provided by an unrestricted grant from the Rut and Klaus Bahlsen Stiftung, Hannover.

The trial has been registered with the German clinical trials register: DRKS-ID DRKS00003240.

Study Population

Patients consulting their GP with acute LBP will be eligible for inclusion in the control group (before GP training) or in the intervention group (after GP training).

Inclusion Criteria

Patients between 18 and 50 years of age with acute (≤ 14 days' duration) nontraumatic, nonspecific LBP were included. We define *LBP* as pain between the lower margin of the rib cage and the gluteal folds (Fig 2).

Exclusion Criteria

Patients will be excluded if they meet any of the following criteria: no written consent; known disease of the spine (osteoporosis, spine surgery in the last 6 months); clinically suspected serious disease (fracture, radiculopathy, cauda equina syndrome, signs of infection); rheumatic diseases of the spine; pregnancy; current treatment by chiropractor or physiotherapist; and medical treatment for back pain in the last 6 months.

Setting and Location

Patient recruitment and therapy will take place in the practices of participating GPs in Lower Saxony, Germany. Blinding of patients of physicians is not possible.

Intervention and Treatment

Manual therapy in Germany is mainly taught by 5 schools with slightly different approaches to diagnosis and treatment.¹⁰ Specialized physicians from different schools participated in an expert panel with the aim of developing a training course specifically for the treatment of LBP. The use of high-velocity thrusts was excluded, as the intervention was intended to consist of simple techniques suitable for physicians with no prior experience of MT.

Fig 2. Definition of the area of nonspecific LBP.

Table 1 Data Collection

Time	Instrument	Additional Data Collected Orally	Methods
T0: baseline	Questionnaire 1	None	Questionnaire will be completed in the practice
T1: 1 wk after treatment	Questionnaire 2 + patient diary	None	Telephone interview
T2: 6 wk after treatment	Questionnaire 3	Further therapies + referral rate + total sick leave (d)	Telephone interview
T3: 12 wk after treatment	Questionnaire 4	None	Telephone interview

Five experts agreed on a diagnostic and therapeutic approach that would be applicable to all patients with LBP. They then planned the intervention, to consist of a single training event with 1 refresher course. The training will be conducted by an experienced MT trainer who participated in the expert panel.

The standardized examination and treatment plan for patients with acute LBP are presented in [Appendix A](#). All patients will receive the standardized examination. The “add-on” treatment in the intervention group will be performed according to this plan.

Outcome Measures and Baseline Data

Sociodemographic data will be collected at the start of the study. Variables include age, sex, family status, qualifications, and employment.

Primary Outcome

The 2 composite end points are (1) the change from baseline in patients’ pain perception at day 3 measured using a numeric pain scale (NPS 0-10) and (2) time until (a) a reduction of 2 points from baseline on the NPS is reached and (b) painkiller use ceases. A change of 2 points on the NPS scale is generally accepted as relevant.¹¹

The intervention will be considered globally superior if (a) the change in NPS on day 3 after the intervention is noninferior compared to the change that is achieved by standard therapy and (b) the second composite end point (time until pain perception is reduced by 2 points on the NPS and painkiller use is stopped) is improved after the intervention.

Secondary Outcomes

Secondary outcomes include pain medication either prescribed or over the counter (as a dichotomous outcome); Hannover functional ability questionnaire¹³; rate of referrals for further treatment; use of concomitant therapy (physiotherapy); duration of sick leave (days); and treatment-related patient satisfaction (directly after treatment, Likert scale 0-10).

Data Collection

The baseline data will be collected before treatment using a questionnaire covering sociodemographic data, pain measured on an NPS (0-10), and current use of painkillers. Patients will be asked to document their pain and painkiller use in a diary provided. Data will be recorded at baseline; and follow-up data will be compiled by telephone interview (based on the distributed questionnaire) after 1, 6, and 12 weeks. Further details on data collection are given in [Table 1](#).

Sample Size Calculation

The estimation of sample size was based on the publication of Schattenkirchner and Milachowski,¹⁴ a multicenter randomized study comparing the effect of 2 analgesic drugs on acute back pain, which used the visual analogue scale as a measure of pain.

An improvement of 1 visual analogue scale point was defined as the *noninferiority margin*. On the basis of a *t* test for independent group comparison and a one-sided type I error of 2.5% and a power of 90%, a sample size of 86 patients per intervention group is necessary to show the noninferiority of the additional MT compared to the standard therapy with a power of 90%. As no literature is available for the second primary end point, the overall sample size was set to the sample size required by the first primary end point. Sample size calculations were performed using Query Advisor, Version 7.0.

To generate sufficient data, we plan to include 10 participating GPs who should each enroll approximately 10 patients during the control and intervention phases, resulting in a total of 100 participants in each of the control and intervention groups.

Statistics

The primary analysis will be performed using the intention-to-treat population. If the follow-up data for the primary outcome are incomplete, the last known NPS value will be carried forward. To show global superiority

of additional MT for both composite end points, the null hypotheses have to be rejected. Specifically, the analysis procedure will include the following steps:

1. First, an analysis of covariance will be performed for the change in NPS value from baseline to day 3 (NPS at baseline to NPS at day 3), adjusting for the covariate baseline value and the independent variables therapy center and therapy group (control or intervention). If the lower value of the 95% confidence interval for the difference between add-on MT and standard therapy alone (add-on manual – standard alone) is above the noninferiority margin of 1, it will be shown that add-on MT is not inferior to standard therapy alone.
2. Second, the time taken to achieve a combined outcome consisting of (a) a 2-point reduction in the NPS score and (b) cessation of painkiller use will be determined. The values for this end point will be analyzed as time-to-event-data. We will use a common Wilcoxon/Breslow test to compare the difference in the spread of times between the standard therapy (control) and the add-on MT (intervention) groups. A sensitivity analysis adjusted for the independent variables therapy group and therapy center will be carried out. The median event times and their 95% confidence intervals will be reported. If this outcome does not occur for an individual patient or the patient leaves the study, this patient will be defined as *censored*.

The secondary outcomes (referral rates, use of further therapies, and patient satisfaction after GP's intervention [at T0]) will be analyzed for both groups by comparing descriptive *P* values of a χ^2 test. Duration of sick leave and results of the FFbH-R (Funktionsfragebogen Hannover) questionnaire will be presented exploratively. A covariate analysis of the data from the questionnaire will be performed with therapy group, therapy center, and baseline values as independent variables and the differences in values at T1 and T2 from those at T0 as dependent variables.

Discussion

This article outlines the rationale and design for a controlled pre-/postintervention study into the use of MT in primary care to treat acute LBP. The lack of clarity regarding the impact of MT on acute, nonspecific LBP^{8,15,16} and the scarcity of trials focusing on the GPs who frequently face patients suffering from LBP motivated us to design this trial. In the ManRück trial, we will explore the effectiveness of standardized MT administered by GPs

who have received expert-approved MT training but are otherwise inexperienced in MT. If this approach is effective, it would offer GPs an additional, cost-effective therapeutic option for a complaint not only from which patients suffer but which also results in feelings of helplessness in GPs¹⁷ because of the high number of patients with LBP and the paucity of evidence-based and effective therapy options.

Regarding the high socioeconomic burden of LBP and of chronic LBP in particular,¹⁸ it would also be interesting to determine whether add-on MT can have an impact on LBP chronification. By assessing the functional capacity of patients until 12 weeks after treatment, we hope to gain some first hints regarding this issue.

An additional strength of our study is the detailed description of the standardized MT technique derived using common expertise from different MT schools in Germany. In contrast to many studies where MT was executed by members of different professions,^{6,19} the experiences of GPs providing MT in our study will be comparable because all of them will have received equivalent MT training.²⁰ The study is necessary because, although research into MT is currently on the increase, there is still a shortage of clinical studies using “real-life” patients in a primary care setting.

The extent of the planned MT training and the number of techniques taught are much lower than in training courses leading to full certification in MT. Our aim, however, is to develop a set of techniques that are easily applicable in daily practice by GPs who do not wish to undergo a full training in MT.

Some authors favor the approach of individualized MT, where patients receive MT that is tailored to their particular clinical presentations and therapists can choose techniques from their repertoires.²¹ We abandoned this approach in favor of the standardized MT to achieve a better comparability of the results. Furthermore, there is some evidence that individualized selection of MT techniques has no influence on the success of treatment.²² Because of limited resources, this study is designed as a pre-/postintervention study instead of an RCT. If MT is shown to be effective in this study, the next step will be an adequately powered RCT.

Conclusion

We describe an intervention for patients with LBP using an expert-approved set of MT techniques. This study seeks to determine whether this intervention can substantially improve the care of patients with acute nonspecific LBP. If successful, this would expand the therapeutic options for patients with acute LBP in primary care.

Funding Sources and Conflicts of Interest

The study was enabled by an unrestricted grant from the Rut and Klaus Bahlsen Stiftung, Hannover, Germany. The funding organization has no influence on the manner in which the study is conducted or on the publication process. CS is a trainer in MT and offers courses. All other authors report no conflicts of interests.

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Appendix A. Examination and MT Protocol for Patients with Acute LBP

In patients with acute lower back pain, history taking should include

History taking:

- duration of pain more than 14 days
- loss of muscle power
- loss of sensitivity
- fever
- traumatic injury
- known osteoporosis
- weight loss, night sweats, or other signs of cancer

If the patient confirms any of the points above, the patient is not eligible for inclusion.

Clinical examination

The examination should be conducted with the patient standing without shoes. If possible, he or she should also wear no trousers and be examined with a free lower back from rib cage to the posterior superior iliac spine.

Examination while patient is standing:

- Inspection of the spine (faulty posture/signs of traumatic injury)
- Indication by the patient of (a) pain localization and (b) radiation where applicable
- Walking on tiptoes and on the heels (to identify damage to S1 and L5)
- Spine test (The therapist places one thumb on the posterior superior Iliac spine [PSIS] and his other thumb on the sacrum, level with his first thumb. The patient lifts the leg under examination as high as possible. If the therapist's thumb does not slide downwards, the test result is positive for sacroiliac dysfunction.)
- Standing forward flexion test (The therapist stands behind the standing patient and places his thumbs on both PSISs. The patient bends forward. If one PSIS moves further forward than the other, the test result is positive for sacroiliac dysfunction.)

Examination while patient is sitting:

- Quadriceps test (patient straightens leg against the examiner's hand)

Examination with patient lying:

- Sensitivity in both legs
- Characteristic muscles for L2/3 -> adduction
- Characteristic muscle for L5 -> musculus extensor hallucis longus

- Lasegue and Bragard test
- Flexibility of the hip joints (interior and exterior rotation)

When clinical signs suggest a radiculopathy, the patient is not eligible for study inclusion

Therapy:

1. Vibrating traction of both legs: Patient is either lying on the back or face down. The therapist takes hold of the legs above the ankle with both hands and pulls the legs with vibration.
2. Abduction or postisometric relaxation: Patient is on the back with bent knees. The patient abducts both legs against resistance from the therapist. The same exercise is then performed with adduction.
3. Mobilization of the iliosacral joint and the lumbar spine: The patient lies on his or her side with upper leg bent 90° at the hip. The therapist stands in front of the patient and places the hand closest to the patient's head on the patient's upper shoulder. The therapist's other hand is placed on the patient's hip. By moving the shoulder and the upper leg of the patient, the therapist can adjust the rotation of the spinal column. The patient should feel the stretch in the painful region and give feedback as to when it becomes uncomfortable. The stretch is held for a few seconds, and then the other side of the back is treated in the same way (Fig 3).

Fig 3. Demonstration of the mobilization technique. (Color version of figure appears online.)